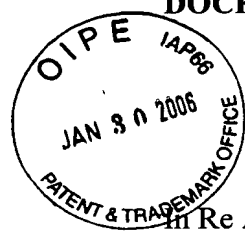


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DOCKET NO.: CEPH-2249 / CP241

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Craig Heacock, et al.

Confirmation No.: **1994**

Application No.: **10/616,776**

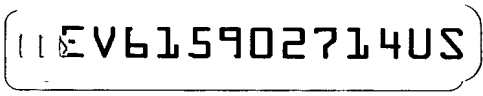
Group Art Unit: **1615**

Filing Date: **July 10, 2003**

Examiner: **Ahmed, Hasan Syed**

For: **Modafinil Pharmaceutical Compositions**

EXPRESS MAIL LABEL NO: EV 615902714 US
DATE OF DEPOSIT: January 30, 2006



☒ MS Amendment ☐ MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY TRANSMITTAL LETTER

- ☐ A Preliminary Amendment.
- ☒ Other: Communication Under 37 C.F.R. § 1.56
- ☐ An Amendment Responsive to the Office Action Dated
- ☐ An Amendment Supplemental to the Paper filed
- ☐ A Substitute Specification (pages 1 -) in clean form.
- ☐ A substitute specification (pages 1 -) with markings.
- ☐ An Abstract is enclosed.
- ☐ replacement sheets of drawings are enclosed comprising figures
- ☐ Request is hereby made to accept black and white photograph(s) in this case, as they are the only practicable medium for illustrating the claimed invention. One (1) set of black and white photographs comprising figure(s) is submitted herewith.
- ☐ Petition is hereby made to accept drawing(s)/photograph(s) in this case.

- ☐ Three (3) sets of color drawing(s)/photograph(s) and black and white photocopy that accurately depicts to the extent possible, the subject matter shown in the color drawing(s)/photograph(s), are enclosed, comprising figures
- ☐ An amendment to the first paragraph in that portion of the Brief Description of the Drawings is also enclosed herewith advising that the patent contains at least one drawing/photograph in color.
- ☐ A Certified Copy of each of the following applications: is enclosed.
- ☐ An Assignee Power of Attorney is enclosed.
- ☐ Information Disclosure Statement.
 - ☐ Attached Form 1449.
 - ☐ A copy of each reference as listed on the attached Form PTO-1449 is enclosed herewith.
- ☐ A Terminal Disclaimer is attached.
- ☐ Appendices as follows:
- ☒ **No Additional Fee is Due.**
- ☐ Applicant(s) has previously claimed small entity status under 37 CFR § 1.27.
- ☐ Applicant(s) by its/their undersigned attorney, claims small entity status under 37 CFR § 1.27 as
- ☐ This application is no longer entitled to small entity status. It is requested that this be noted in the files of the U.S. Patent and Trademark Office.

				SMALL ENTITY		NOT SMALL ENTITY	
	REMAINING AFTER AMENDMENT	HIGHEST PAID FOR	EXTRA	RATE	FEE	RATE	FEE
TOTAL CLAIMS		(20 MINIMUM)		\$25 EACH	\$	\$50 EACH	\$
INDEP. CLAIMS		(3 MINIMUM)		\$100 EACH	\$	\$200 EACH	\$
FIRST PRESENTATION OF MULTIPLE DEPENDENT				\$180	\$	\$360	\$
<input type="checkbox"/> ONE MONTH EXTENSION OF TIME				\$60	\$	\$120	\$
<input type="checkbox"/> TWO MONTH EXTENSION OF TIME				\$225	\$	\$450	\$
<input type="checkbox"/> THREE MONTH EXTENSION OF TIME				\$510	\$	\$1020	\$
<input type="checkbox"/> FOUR MONTH EXTENSION OF TIME				\$795	\$	\$1590	\$
<input type="checkbox"/> FIVE MONTH EXTENSION OF TIME				\$1080	\$	\$2160	\$
<input type="checkbox"/> LESS ANY EXTENSION FEE ALREADY PAID				minus	(\$)	minus	(\$)
<input type="checkbox"/> TERMINAL DISCLAIMER				\$65	\$	\$130	\$
<input type="checkbox"/> OTHER FEE OR SURCHARGE AS FOLLOWS:							
TOTAL FEE DUE					\$		\$

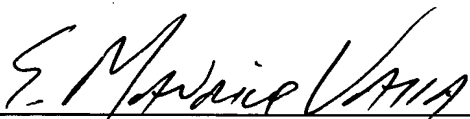
- ☐ A check in the amount of \$.00 is attached. Please charge any deficiency or credit any overpayment to Deposit Account 23-3050.
- ☐ Please charge Deposit Account No. 23-3050 in the amount of .00 . This sheet is attached in duplicate.
- ☒ The Commissioner is hereby authorized to charge any deficiency or credit any overpayment of the fees associated with this communication to Deposit Account No. 23-3050.
- ☐ Petition is hereby made under 37 CFR § 1.136(a) (fees: 37 CFR § 1.17(a)(1)-(4)) to extend the time for response to the Office Action of _____ to and through _____ comprising an extension of the shortened statutory period of _____ month(s).

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- ☒ The Commissioner is hereby requested to grant an extension of time for the appropriate length of time, should one be necessary, in connection with this filing or any future filing submitted to the U.S. Patent and Trademark Office in the above-identified application during the pendency of this application. The Commissioner is further authorized to charge any fees related to any such extension of time to Deposit Account 23-3050. This sheet is provided in duplicate.

Date: January 30, 2006



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PATENT



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COMMUNICATION UNDER 37 C.F.R. § 1.56

As discussed with Examiner Ahmed in a teleconference dated January 13, 2006, Applicants wish to advise the Patent and Trademark Office of the status of litigation between Cephalon, Inc. ("Cephalon"), the assignee of the instant application, and Ranbaxy Laboratories Limited ("RLL"), which filed the Abbreviated New Drug Application (ANDA) referenced in Applicants' Petition to Make Special.

On December 16, 2005, Applicants filed a Petition to Make Special Because of Actual Infringement under 37 C.F.R. § 1.102 and M.P.E.P § 708.2. As discussed in the Attorney's Declaration and in the Statement of Facts that were filed in support of that Petition, RLL is one of several generic manufacturers to have filed Abbreviated New Drug Applications (ANDAs) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) seeking FDA approval to market modafinil drug products. As part of that ANDA, RLL certified under FDCA Section 505(j)(2)(A)(vii), paragraph IV that Cephalon's U.S. Patent No. RE37,516 E ("the '516 patent") is invalid or will not be infringed by the modafinil product that RLL sought to have approved. Pursuant to filing its ANDA, RLL notified Cephalon, in a letter dated March 21, 2003, that it had filed a paragraph IV certification. In response to the filing of that ANDA, Cephalon sued RLL for infringement of the '516 patent under 35 U.S.C. § 271(e)(2). See Statement of Facts, ¶¶ 4, 5.

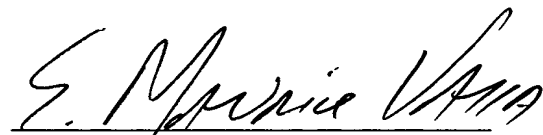
Subsequent to the filing of Applicants' Petition to Make Special, Cephalon and RLL settled the litigation involving the '516 patent. The settlement was announced in a press release dated December 22, 2005. However, Applicants' undersigned representative did not become aware of the settlement until January 4, 2006, subsequent to receiving notification from the USPTO dated December 28, 2005 that the Petition had been granted (received on January 3, 2006).

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In the opinion of Applicants' undersigned representative, the dismissal of Cephalon's suit for infringement of the '516 patent has no impact on the theory of actual infringement that formed the basis of Applicants' Petition to Make Special, because the instant application was not at issue in that litigation. Now that the Petition has been granted, and the application has proceeded into examination on the merits, Applicants believe that there is no reason for the Patent Office to reconsider its decision to examine this case on an accelerated basis. However, Applicants file this paper to bring these facts to the Examiner's attention, in the interest of candor and full disclosure.

January 30, 2006



S. Maurice Valla
Registration No. 43,966